

Investigating the biomechanics function of the plate-type external fixator in the treatment of tibial fractures: a biomechanical study

Di Shi

Department of Orthopedics, the Second Affiliated Hospital of Air Force Medical University, China

Kaiyuan Liu

State Key for Strength and Vibration of Mechanical Structures, School of Aerospace Engineering, Xi'an Jiaotong University, Shaanxi, China

Haomeng Zhang

Department of Orthopedics, the Second Affiliated Hospital of Air Force Medical University, Shaanxi, China

Xinli Wang

Department of Orthopedics, the second affiliated hospital of Air Force Medical University, Shaanxi, China

Guochen Li

Department of Orthopedics, the second affiliated hospital of Air Force Medical University, Shaanxi, China

Lianhe Zheng (✉ Xiaowandou@163.com)

Department of Orthopedics, the Second Affiliated Hospital of Air Force Medical University, Shaanxi, China <https://orcid.org/0000-0002-9109-8650>

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Abstract

Background People have been pursuing to design an external fixator with the optimal biomechanics function and the lowest profile, since the fracture healing is dependent on the stability and durability of fixation and a low profile is more acceptable to patients. The plate-type external fixator, a novel prototype of an external tibial fixation device, is a low profile construct. However, the biomechanical properties remained unclear. The objective of the study was to investigate stiffness and strength of the plate-type external fixator and the unilateral external fixator. We hypothesized that the plate-type external fixator could provide higher stiffness, while retaining sufficient strength.

Methods Fifty-four cadaver tibias underwent a standardized midshaft osteotomy to create a fracture gap model to simulate a comminuted diaphyseal fracture. All specimens were randomly divided into three groups of eighteen specimens each and stabilized with either the unilateral external fixator or the two configurations of the plate-type external fixator. Six specimens of each configuration were tested to determine fixation stiffness in axial compression, four-point bending, and torsion, respectively. Afterwards, dynamically loading until failure was performed in each load mode to determine construct strength and failure modes.

Results The plate-type external fixator provided higher stiffness and strength compared with the traditional unilateral external fixator. The highest biomechanics was observed for the classical plate-type external fixator, with the extended plate-type external fixator close behind.

Conclusions The plate-type external fixator is stiffer and stronger than the traditional unilateral external fixator under axial compression, four-point bending and torsion loading conditions.

Background

Traditionally, external fixators have been selected to be osteosynthesis devices in the treatment of open tibial fractures and certain closed tibial fractures with severe injury of soft tissue [1, 2]. External fixation devices provide a promising and satisfactory alternative for better soft tissue care and preserving periosteal perfusion to the regions of fracture [2, 3]. They can be a choice for interim or definite device of fracture fixation [4]. However, previous studies have demonstrated that the stiffness of a fixation device is a principal determinant of interfragmentary movement, which has a significant effect on the mechanism and progression of fracture healing [5, 6]. Excessive interfragmentary movement, due to insufficient stiffness of external fixators, can result in deficient callus formation, eventually leading to delayed union or even nonunion with ultimate implant failure [7–9]. Meanwhile, an external fixator with high strength can contribute to durable fixation to allow for progressive functional training [10]. Besides, the high profile of the implants, which tends to bring much inconvenience to patients during dressing and ambulation, leads to low acceptance of patients [11, 12].

External fixators used in present clinical practice are linked to various limitations, including insufficient fixation stiffness and strength, leading to poor healing, or high profile of the constructs, resulting in non-

patient friendly physical burden [13–17]. It is therefore essential to design a novel prototype of an external fixator for tibial fracture to increase the rigidity and strength, while reducing the profile of the fixation constructs. The plate-type external fixator, a novel prototype of an external tibial fixation device, with a lower profile than the traditional unilateral external fixator, was designed for greater construct stability and durability by our research group.

Since the biomechanics function of the plate-type external fixator remained unclear, the study was performed to investigate the biomechanical parameters of the novel external fixator by comparing with the unilateral external fixator, for fixation with a unilateral external fixator is common for fractures in the diaphyseal region of the tibia [6, 18]. We hypothesized that the plate-type external fixator could provide higher fixation stability and durability than did the traditional external tibial fixation devices.

Methods

Fracture model

A total of fifty-four fresh and unembalmed tibias were selected from fifty-four voluntarily donated adult male cadavers (Department of Anatomy, Air Force Medical University, Xi'an, China) between the ages of 18 and 50. The average length of the selected tibias was 340 mm (range from 310 mm to 375 mm). All selected tibias specimens were examined for the bone mineral density and excluded of osteoporosis by means of a dual energy X-ray absorptiometry (LUNAR IDAX, GE Inc., Boston, Massachusetts, USA), and then cleaned of any soft tissues for this study. T-score, defined as the standard deviation value between the bone mineral density value measured and that of healthy adults between the ages of 30 and 35, was selected to represent the values of bone mineral density, since that is an important parameter to identify osteoporosis and commonly used to determine whether bone density is normal in clinical practice. A T-score value more than -1 implies normal bone, and a T-score more than -2.5 and less than -1 is related to osteopenia, while a T-score less than -2.5 tends to indicate osteoporosis.

The novel prototype of an external tibial fixation device, namely the plate-type external fixator, consists of a proximal tibial fixation lath with a transverse slat in the proximal and a distal tibial fixation lath with a transverse slat in the distal. The distal end of the proximal fixation slat is equipped with a slot, and the proximal end of the distal fixation slat can insert into the slot and slide along it to adjust the length of the fixator to different length of the human lower limbs. Besides, the tibial fixation laths and the transverse slats are both equipped with locking screw holes, and all the screws used are fully threaded self-tapping locking screws (Fig. 1). With a lower profile than the traditional unilateral external fixator, the novel external tibial fixator, designed to match perfectly with human crus, could be expected to make it easier to adjust the plate close to the bone surface. For this study, we lengthened the plate-type external fixator by 30 mm, namely twofold the hole spacing, to make clear whether the extended plate-type external fixator could also provide sufficient stiffness and strength.

The fifty-four tibias were randomly divided into three groups of eighteen specimens each, with fixation by the classical plate-type external fixator (CPF), the extended plate-type external fixator (EPF) or the unilateral external fixator (UEF). Subsequently, the eighteen specimens of each configuration group were randomly divided into three groups of six specimens each, and then tested in axial compression, four-point bending, and torsion, respectively.

A standardized midshaft osteotomy by means of the oscillating saw was performed for all the tibias to create a 20 mm fracture gap with the aid of a vernier caliper, simulating a comminuted tibial shaft fracture and making sure no contact between both ends of the fracture. Eighteen specimens were stabilized with the 13-hole stainless steel classical plate-type external fixator (300 mm in length, 21 mm in width, 10 mm in thickness, Kangding medical alliance Co., Ltd., Shanghai, China), with three 5 mm diameter stainless steel locking screws in the first, third and fifth locking holes proximally and three 5 mm diameter stainless steel locking screws in the ninth, eleventh and thirteenth locking holes distally. Eighteen specimens were stabilized with the 15-hole stainless steel extended plate-type external fixator (330 mm in length, 21 mm in width proximally and 16 mm in width distally, 10 mm in thickness proximally and 5 mm in thickness distally, Kangding medical alliance Co., Ltd., Shanghai, China), with three 5 mm diameter stainless steel locking screws in the second, fourth and sixth locking holes proximally and three 5 mm diameter stainless steel locking screws in the tenth, twelfth and fourteenth locking holes distally. Both plate-type external fixators have a hole spacing of 15 mm.

Eighteen specimens were stabilized with the stainless steel unilateral external fixator (Kangding medical alliance Co., Ltd., Shanghai, China) in our control group. Three stainless steel half-pins (5 mm in diameter) were fixed per fragment and linked with pin clamps to a stainless steel rod (300 mm in length, 11 mm in diameter). The positions of the half-pins corresponded to the locking screws of the classical plate-type external fixator in the first, third and fifth holes proximally and in the ninth, eleventh and thirteenth holes distally.

The choice of three locking screws/half-pins per fracture fragment in our study adhered to the AO principles of external fixation that a minimum of three screws were needed to achieve a stable fixation on either fragment of the fracture. The AO recommended having a screw near and a screw far from the fracture end in both fragments, however, for the sake of comparison, the most distant screws were inserted into the second and the fourteen locking holes in the extended plate-type external fixator group, instead of the first and the fifteenth locking holes, so the same three locking screws/half-pins positions were used in both fragments of the fracture among the three fracture fixation configuration groups. We accepted that this was a limitation and the adjustment of the locking screws may influence the fixation stiffness of the extended plate-type external fixator.

The offset distance was restricted to 15 mm between the bone surface and external plates/rods to allow for the swelling of soft tissue without disturbance with the configuration and provide sufficient space for postoperative care. We chose an offset of 15 mm instead of 20 mm or 30 mm for the purpose of increasing the fixation stability of the configuration to prevent excessive interfragmentary movements [4,

19, 20]. The inner locking screws/half-pins were inserted at a distance of 20 mm from the fracture end. The locking screws/half-pins used were long enough to ensure adequate purchase of the bilateral cortex.

Mechanical testing

The proximal and distal ends of all the fracture fixation configurations were potted in polymethylmethacrylate for mechanical testing (Fig. 2) [6]. Subsequently, the bone-implant constructs were mounted in the testing machine with the aid of a customized jig. Classical plate-type external fixation constructs, extended plate-type external fixation constructs and unilateral external fixation constructs were tested to determine fixation stiffness under three loading conditions (axial compression, four-point bending and torsion) (Fig. 3) [6, 21]. The relative displacements at the fracture site were recorded on the computer, to calculate the stiffness of the configuration. Subsequently, three constructs underwent dynamically loading until failure under each loading mode to determine construct strength and failure modes. Construct strength was defined as the peak load as soon as construct failure happened during progressive dynamic loading to failure under each loading mode. Configuration failure was defined either by catastrophic fracture or by nonrecoverable deformation in the region of fracture, whichever happened first [5, 22–24].

Axial compression test

Both ends of the constructs were mounted with use of a customized axial compression jig in the Zwick/Roell-Z005 electronic materials testing machine (Ulm, Germany) (Figs. 3A and 4). The applied loading was gradually increased from 0 N to a maximum load of 700 N, corresponding to the weight of a 70 kg person during one-legged stance [25], with a rate of 0.1 mm/s for six cycles. The interfragmentary displacements at the fracture site were determined by means of the laser displacement sensors (LK-G10, KEYENCE Inc., JAPAN) attached to both the ends of fracture gap. Axial compression stiffness was determined by dividing the axial load values by vertical strain values, and was expressed in N/mm.

After the static test, sinusoidal loading with a constant load amplitude was applied for each construct. Every 100 loading cycles, the load amplitude was increased stepwise by 100 N until configuration failure occurred, while the pre-load was applied to 50 N, for the purpose of ensuring construct failure happened within a reasonable number of loading cycles (<10,000) by stepwise increasing to failure [5, 21].

Four-point bending test

The constructs were placed in turn by means of a customized bending jig on the Zwick/Roell-Z005 electronic materials testing machine (Ulm, Germany) (Figs. 3B and 5). The bending moment is calculated by multiplying the bending force by the bending length. The distance between the lower supports was set to 200 mm, while the upper supports were separated by 100 mm. The bending length, defined as the distance between the upper and the lower supports on either side of the fracture, was set to 50 mm. The

bending force applied was constantly increased up to 400 N, corresponding to the bending moment of 20 Nm, at a rate of 1 mm/min. Bending stiffness was calculated by dividing the bending moment by the bending angle, and was expressed in Nm/deg [26, 27]. Afterwards, sinusoidal loading with a constant amplitude was applied for each configuration. Every 100 loading cycles, the load amplitude was increased gradually by 1 Nm until configuration failure occurred, while the pre-load was applied to 1 Nm [5].

Torsion test

The torsional testing was performed with use of a CTS–500 microcomputer controlled torsion test machine (Hualong testing instrument Co., Ltd., Shanghai, China) equipped with a custom-made torsional jig, with the proximal and distal ends of the constructs being rigidly clamped by means of that (Figs. 3C and 6). The implemented torque was constantly increased from 0 Nm to 10 Nm with a rate of 0.1 deg/s for six cycles. Torsional stiffness was obtained by dividing the torque value by the relative rotation value, and was expressed in Nm/deg. Subsequently, sinusoidal loading with a constant amplitude was applied for each configuration. Every 100 loading cycles, the load amplitude was increased step by step by 1 Nm until construct failure occurred, while the pre-load was implemented to 1 Nm [5].

Statistical analysis

The collected data were statistically analyzed with SPSS 23.0 software (SPSS, Chicago, Illinois, USA). Firstly, the results were tested for normality and homogeneity of variance. When according with normal distribution and homogeneity of variance, the data were analyzed by means of one-way analysis of variance to determine the significance difference of the means of three groups. The LSD test was used to perform post hoc testing if necessary. The level of significance of $p < 0.05$ was thought to be statistically significant.

Results

Age and bone mineral density

The mean age was quite similar for the CPF group (33.0 years), the EPF group (31.0 years) and the UEF group (35.5 years). One-way analysis of variance demonstrated that there was no significant difference ($F = 0.311$, $p = 0.737$) among three fixation groups. The results were displayed in table 1 in table form.

There was also no significant difference ($F = 0.100$, $p = 0.905$) in mean T-score between the CPF group (-0.81), the EPF group (-0.84), and the UEF group (-0.83), which was proved by means of one-way ANOVA. Table 2 displayed the results in table form. Since the mean T-score values of three fixation group were all more than -1 , we can conclude all the specimens were normal bone and excluded of osteoporosis.

Construct stiffness

One-way analysis of variance demonstrated that the mean axial stiffness was significantly ($F = 24.642$, $p < 0.0001$) different for the CPF group (1898.8 N/mm), the EPF group (1715.8 N/mm), and the UEF group (1157.8 N/mm). The axial stiffness parameters of three groups were displayed in Table 3 in table form and in Fig. 4A in chart form. The LSD test revealed that the axial stiffness of the CPF group was statistically ($p < 0.0001$) higher than that of the UEF group by 0.64. The axial parameter of the EPF group was also statistically ($p < 0.0001$) greater than that of the UEF group by 0.48.

There was a significant ($F = 17.365$, $p < 0.0001$) difference in mean four-point bending stiffness between the CPF group (26.7 Nm/deg), the EPF group (24.1 Nm/deg), and the UEF group (15.0 Nm/deg), which was proved by means of one-way ANOVA. Table 4 displayed the parameters in table form, while Fig. 4B showed them in chart form. Based on the results of one-way ANOVA, the post hoc test was performed with use of LSD test for pairwise comparison, which revealed that the bending stiffness of the CPF group was significantly ($p < 0.0001$) 78% greater than that of the UEF group. The stiffness value of the EPF group was also significantly ($p = 0.001$) 61% higher than that of the UEF group.

One-way ANOVA revealed a statistical ($F = 130.824$, $p < 0.0001$) difference in mean torsional stiffness between the CPF group (3.0 Nm/deg), the EPF group (2.6 Nm/deg), and the UEF group (1.3 Nm/deg). The results were displayed in Table 5 and Fig. 4C. Subsequently, pairwise comparison, by means of LSD test, demonstrated that the torsional stiffness of the CPF group was statistically ($p < 0.0001$) larger than that of the UEF group by 1.31. The stiffness value of the EPF group was also statistically ($p < 0.0001$) larger than that of the UEF group by 1.

Construct strength

In axial compression, the strength of the CPF group (2792.2N) was statistically ($p < 0.0001$) higher than that of the UEF group (1769.0 N) by 0.58. The axial parameter of the EPF group (2560.5 N) was also statistically ($p < 0.0001$) greater than that of the UEF group by 0.45. The results were displayed in Table 6 and Fig. 5A. Both CPF and EPF constructs failed by catastrophic fracture of the diaphysis through the screw hole (Fig. 6A). After fracture, CPF constructs displayed no implant hardware failure in four specimens, screw breakage in one specimen and screw bending in one specimen, while EPF constructs showed no implant hardware failure in one specimens, screw and plate bending in three specimens and screw breakage in two specimens. UEF constructs failed as a result of nonrecoverable fracture gap closure due to half-pin and rod bending in five specimens and fracture of the diaphysis in one specimen.

In four-point bending, the construct strength of the CPF group (58.2 Nm) was significantly ($p < 0.0001$) 22% greater than that of the UEF group (47.9 Nm). The strength value of the EPF group (56.4 Nm) was also significantly ($p < 0.0001$) 18% higher than that of the UEF group. Table 7 displayed the parameters in table form, while Fig. 5B showed them in chart form. All constructs failed by catastrophic fracture of the diaphysis (Fig. 6B). After fracture, all CPF constructs displayed no implant hardware failure, EPF constructs showed no implant hardware failure in three specimens, screw bending in three specimens,

while UEF constructs showed half-pin and rod bending in four specimens and half-pin breakage and rod bending fracture in two specimen.

In torsion, the strength of the CPF group (34.2 Nm) was statistically ($p < 0.0001$) larger than that of the UEF group (24.2 Nm) by 0.41. The strength value of the EPF group (30.0 Nm) was also statistically ($p < 0.0001$) larger than that of the UEF group by 0.24. The results were displayed in Table 8 and Fig. 5C. CPF constructs failed by screw and plate bending in four specimens, screw breakage in one specimen and spiral fracture in one specimen. EPF constructs failed as a result of screw and plate bending in two specimens, screw breakage and plate bending in two specimen and spiral fracture in two specimen. UEF constructs showed oblique fracture in four specimens (Fig. 6C) and half-pin and rod bending in two specimens, resulting in nonrecoverable deformation in the region of fracture.

Discussion

The results of the study supported the hypothesis that the plate-type external fixator could remarkably increase the stiffness of the fracture fixation construct while retaining sufficient strength. In this experiment, the two configurations of the plate-type external fixator exhibited higher stiffness and strength than did the traditional unilateral external fixator in axial compression, four-point bending and torsion. According to a report by Devakara R. Epari et al, the relationship between the fracture healing and the axial stiffness of the external fixation constructs was not simple linear relation, but approximate to an inverse quadratic polynomial [6]. This equation revealed that the optimal axial compressive stiffness was 2050 N/mm, which can result in an optimizing fracture healing outcome. Therefore, optimizing the axial stiffness of fixation constructs may be significant for the satisfactory healing outcome [28–31]. In our study, the classical plate-type external fixator provided an axial stiffness value of up to 1898.8 N/mm. Besides, the axial stiffness of the extended plate-type external fixator was investigated to be 1715.8 N/mm, which was lower than that of the classical plate-type external fixator, but markedly higher than that of the unilateral external fixator (1157.8 N/mm). The axial stiffness of the classical plate-type external fixator was quite close to the optimal axial stiffness value, with the extended plate-type external fixator close behind.

The results of the previous studies reported that the healing outcomes tended to get worse with decreasing bending stiffness [6]. Our study revealed that the four-point bending stiffness of the plate-type external fixator was significantly higher than that of the unilateral external fixator. This suggested that bone healing could be better stimulated by the fixation with the two configurations of the plate type external fixator.

The torsional stiffness values of the external fixators reported in the previous literature varied in a range from 1 Nm/deg to 4 Nm/deg [6, 32]. The healing outcomes appeared to get better with increasing torsional stiffness in the range. The torsional stiffness values of all of the bone-implant constructs in our research were within the range, and the plate-type external fixator provided remarkably higher torsional stiffness than did the unilateral external fixator. This suggested that the plate-type external fixator could

be a promising alternative to the traditional unilateral external fixator to be used for external fixation of tibial fractures, as the increased torsional stiffness was more stimulatory to the bone healing.

According to our study, the two configurations of the plate-type external fixator could provide higher strength than did the unilateral external fixator in axial compression, four-point bending and torsion. We can conclude that the plate-type external fixator was stronger than the unilateral external fixator to contribute to more durable fixation to allow for progressive functional training for more intensity and duration. Therefore, we have reason to believe that the plate-type external fixator could provide sufficient stability to allow for partial weight load support originally, and gradual progression to full weight load.

In our study, the length of the extended plate-type external fixator was longer than of the classical plate type external fixator by 30 mm, while the distal thickness of that was 50% lower. When we slid the distal tibial fixation lath along the slot to lengthen the plate-type external fixator, the fixation stiffness and strength were reduced to 1715.8 N/mm and 2560.5 N in axial compression, 24.1 Nm/deg and 56.4 Nm in four-point bending, 2.6 Nm/deg and 30.0 Nm in torsion, respectively, which were lower than that of the classical plate-type external fixator, but significantly higher than the unilateral external fixator. Therefore, we can conclude that the two configurations of the plate-type external fixator provided higher stiffness and strength than did the traditional unilateral external fixator. Furthermore, our study showed that the stiffness and strength of the construct would be lower as the thickness of the plate became thinner. However, the extended plate-type external fixator was still stiffer and stronger than that of the traditional unilateral external fixator.

Previous studies investigating how the fixation stiffness and strength can be influenced showed that several factors affected the stability and durability of the bone-implant constructs [1, 19, 20, 33–38]. The working length, defined as the distance between the first two screws on both sides of the fracture gap, has a noticeable impact on the fixation biomechanics function. Meanwhile, altering the offset distance between the plate and the bone surface could significantly change the stability and durability of the bone-implant construct. Moreover, the amount and position of the screws, fracture gap size, and the material properties of the external fixator all have influence on the biomechanics parameters. In our study, the working length of the three fixation groups was all set to 60 mm, namely fourfold the hole spacing. Meanwhile, a 15 mm offset was all kept between the plate/rod and the bone surface in three fixation groups. Besides, the amount of the screws, fracture gap size, and the material properties were the same in the three external fixation groups. Therefore, it could be concluded that the plate-type external fixator can provide more sufficient stability and durability than did the unilateral external fixator, since the stiffness and strength of the plate-type external fixator was higher in axial compression, four-point bending and torsion.

There were still several limitations in the study. On the one hand, the investigation of the stiffness and strength was performed in vitro and all specimens were cleaned of any soft tissues, resulting in the load applied in this fixation model not completely stimulating the multifaceted load pattern in vivo. On the other hand, the fixation parameters were only investigated for the non-osteoporotic specimens. Ideally, we

should also investigate the biomechanics parameters for the osteoporotic specimens, since the stiffness and strength were highly affected by bone quality.

Despite with the aforementioned limitations, we believed the model used in our study was appropriate for comparing the stiffness and strength between the plate-type external fixator and the unilateral external fixator. The biomechanics parameters were investigated individually for the mainly load-bearings that a fracture-fixator configuration might sustain, namely axial compression loading, bending loading and torsional loading. The parameters were very useful in developing a comprehensive understanding of the relative benefits of the plate-type external constructs under multifaceted loading modes in vivo, which were some combination of these forces investigated in our study. Therefore, we believed that the results based on this study were appropriate to be extrapolated to human applications and valuable for clinical judgment.

Conclusion

Until now people have been designing an external fixator with the optimal biomechanics function and the lowest profile. In this study, the plate-type external fixator was significantly stiffer and stronger than the traditional unilateral external fixator, and the stiffness of which was closer to the optimal value. Moreover, the low profile of the plate-type external fixator, reducing the inconvenience during dressing and ambulation, could increase comfort and improve acceptance of patients. In conclusion, using the plate-type external fixator could provide a promising and satisfactory alternative to the traditional unilateral external fixator, since its more sufficient stiffness and strength to promote bone healing and lower profile to make it more acceptable to patients.

Abbreviations

CPF: The classical plate-type external fixator; EPF: The extended plate-type external fixator; UEF: The unilateral external fixator; ANOVA: Analysis of variance.

Declarations

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Availability of data and material

The data that support the results of the research are available within the article.

Author contribution

DS: modeling, mechanical testing, data analysis and writing.

KL: data collection, mechanical testing and photograph process.

HZ: modeling, statistical process and photograph process.

XW: data collection and photograph process.

GL: statistical process and modeling.

LZ: study design and final approval of the manuscript.

All authors have read and approved the final manuscript.

Competing interests

The authors have declared that they had no potential conflicts of interest.

Consent for publication

Not applicable.

Ethics approval and consent to participate

All experiments were approved by the Ethical Committee of the Second Affiliated Hospital of Air Force Medical University and carried out according to the corresponding principles and ethical standards.

References

- 1.Kenwright J, Gardner T. Mechanical influences on tibial fracture healing. Clin Orthop Relat Res. [Comparative Study; Journal Article]. 1998 1998–10–01(355 Suppl):S179–90.
- 2.Luo P, Xu D, Wu J, Chen Y. Locked plating as an external fixator in treating tibial fractures. MEDICINE. 2017;96(49):e9083.
- 3.Schmal H, Strohm PC, Jaeger M, Sudkamp NP. Flexible fixation and fracture healing: do locked plating ‘internal fixators’ resemble external fixators? J ORTHOP TRAUMA. [Comparative Study; Journal Article;

Review]. 2011 2011-02-01;25 Suppl 1:S15-20.

4. Bottlang M, Doornink J, Fitzpatrick DC, Madey SM. Far Cortical Locking Can Reduce Stiffness of Locked Plating Constructs While Retaining Construct Strength. *The Journal of Bone and Joint Surgery-American Volume*. 2009;91(8):1985-94.

5. Epari DR. Timely Fracture-Healing Requires Optimization of Axial Fixation Stability. *The Journal of Bone and Joint Surgery (American)*. 2007 2007-07-01;89(7):1575.

6. Button G, Wolinsky P, Hak D. Failure of Less Invasive Stabilization System Plates in the Distal Femur: A Report of Four Cases. *J ORTHOP TRAUMA*. 2004 2004-01-01;18(8):565-70.

7. Sommer C, Gautier E, Müller M, Helfet DL, Wagner M. First clinical results of the Locking Compression Plate (LCP). *INJURY*. 2003;34:43-54.

8. Zderic I, Oh J, Stoffel K, Sommer C, Helfen T, Camino G, et al. Biomechanical Analysis of the Proximal Femoral Locking Compression Plate: Do Quality of Reduction and Screw Orientation Influence Construct Stability? *J ORTHOP TRAUMA*. 2018 2018-01-01;32(2):67-74.

9. Bottlang M, Doornink J, Lujan TJ, Fitzpatrick DC, Marsh JL, Augat P, et al. Effects of Construct Stiffness on Healing of Fractures Stabilized with Locking Plates. *The Journal of Bone and Joint Surgery-American Volume*. 2010;92(Suppl 2):12-22.

10. Qiu XS, Yuan H, Zheng X, Wang JF, Xiong J, Chen YX. Locking plate as a definitive external fixator for treating tibial fractures with compromised soft tissue envelop. *Arch Orthop Trauma Surg*. [Journal Article; Research Support, Non-U.S. Gov't]. 2014 2014-03-01;134(3):383-8.

11. Tulner SA, Strackee SD, Kloen P. Metaphyseal locking compression plate as an external fixator for the distal tibia. *INT ORTHOP*. [Journal Article]. 2012 2012-09-01;36(9):1923-7.

12. Apivatthakakul T, Sananpanich K. The locking compression plate as an external fixator for bone transport in the treatment of a large distal tibial defect: a case report. *INJURY*. [Case Reports; Journal Article]. 2007 2007-11-01;38(11):1318-25.

13. Feng W, Fu L, Liu J, Qi X, Li D, Yang C. Biomechanical evaluation of various fixation methods for proximal extra-articular tibial fractures. *J SURG RES*. 2012;178(2):722-7.

14. Sirisreetreerux N, Sa-Ngasoongsong P, Chanplakorn P, Kulachote N, Laohajaroensombat S, Suphachatwong C, et al. Using a reconstruction locking compression plate as external fixator in infected open clavicle fracture. *Orthop Rev (Pavia)*. [Case Reports]. 2013 2013-06-07;5(2):52-5.

15. Ma C, Wu C, Tu Y, Lin T. Metaphyseal locking plate as a definitive external fixator for treating open tibial fractures—Clinical outcome and a finite element study. *INJURY*. 2013;44(8):1097-101.

- 16.Zhang J, Ebraheim NA, Li M, He X, Liu J, Zhu L, et al. External Fixation Using a Locking Plate: A Reliable Way in Treating Distal Tibial Fractures. J ORTHOP TRAUMA. [Journal Article]. 2015 2015–11–01;29(11):e454–8.
- 17.Wright JG. Long-term outcome after tibial shaft fracture. J BONE JOINT SURG AM. [Comment; Letter]. 2003 2003–07–01;85(7):1396, 1396.
- 18.Stoffel K, Dieter U, Stachowiak G, Gächter A, Kuster MS. Biomechanical testing of the LCP—how can stability in locked internal fixators be controlled? INJURY. 2003;34:11–9.
- 19.Stoffel K, Lorenz KU, Kuster MS. Biomechanical considerations in plate osteosynthesis: the effect of plate-to-bone compression with and without angular screw stability. J ORTHOP TRAUMA. [Comparative Study; Journal Article; Research Support, Non-U.S. Gov't]. 2007 2007–07–01;21(6):362–8.
- 20.Fitzpatrick DC, Doornink J, Madey SM, Bottlang M. Relative stability of conventional and locked plating fixation in a model of the osteoporotic femoral diaphysis. CLIN BIOMECH. 2009;24(2):203–9.
- 21.Gosling T, Schandelmaier P, Marti A, Hufner T, Partenheimer A, Krettek C. Less invasive stabilization of complex tibial plateau fractures: a biomechanical evaluation of a unilateral locked screw plate and double plating. J ORTHOP TRAUMA. [Journal Article; Research Support, Non-U.S. Gov't]. 2004 2004–09–01;18(8):546–51.
- 22.Hasenboehler E, Smith WR, Laudicina L, Philips GC, Stahel PF, Morgan SJ. Fatigue behavior of Ilizarov frame versus tibial interlocking nail in a comminuted tibial fracture model: a biomechanical study. J ORTHOP SURG RES. 2006 2006–01–01;1(1):16.
- 23.Sun H, He Q, Zhang B, Zhu Y, Zhang W, Chai Y. A biomechanical evaluation of different fixation strategies for posterolateral fragments in tibial plateau fractures and introduction of the 'magic screw'. The Knee. 2018;25(3):417–26.
- 24.Walpole SC, Prieto-Merino D, Edwards P, Cleland J, Stevens G, Roberts I. The weight of nations: an estimation of adult human biomass. BMC PUBLIC HEALTH. [Comparative Study; Journal Article]. 2012 2012–06–18;12:439.
- 25.Oh J, Sahu D, Ahn Y, Lee S, Tsutsumi S, Hwang J, et al. Effect of fracture gap on stability of compression plate fixation: A finite element study. J ORTHOP RES. 2009:n/a-n/a.
- 26.Sellei RM, Kobbe P, Dadgar A, Pfeifer R, Behrens M, von Oldenburg G, et al. External fixation design evolution enhances biomechanical frame performance. INJURY. [Journal Article; Research Support, Non-U.S. Gov't]. 2015 2015–09–01;46 Suppl 3:S23–6.
- 27.Hussain MS, Dailey SK, Avilucea FR. Stable Fixation and Immediate Weight-Bearing After Combined Retrograde Intramedullary Nailing and Open Reduction Internal Fixation of Noncomminuted Distal Interprosthetic Femur Fractures. J ORTHOP TRAUMA. 2018;32(6):e237–40.

- 28.Probst A, Jansen H, Ladas A, Spiegel HU. Callus formation and fixation rigidity: a fracture model in rats. J ORTHOP RES. [Journal Article; Research Support, Non-U.S. Gov't]. 1999 1999-03-01;17(2):256-60.
- 29.Sha M, Guo Z, Fu J, Li J, Fan Yuan C, Shi L, et al. The effects of nail rigidity on fracture healing in rats with osteoporosis. ACTA ORTHOP. 2009;80(1):135-8.
- 30.Snow M, Thompson G, Turner PG. A Mechanical Comparison of the Locking Compression Plate (LCP) and the Low Contact-Dynamic Compression Plate (DCP) in an Osteoporotic Bone Model. J ORTHOP TRAUMA. 2008 2008-01-01;22(2):121-5.
- 31.Schmidt U, Penzkofer R, Bachmaier S, Augat P. Implant Material and Design Alter Construct Stiffness in Distal Femur Locking Plate Fixation: A Pilot Study. CLIN ORTHOP RELAT R. 2013;471(9):2808-14.
- 32.Ahmad M, Nanda R, Bajwa AS, Candal-Couto J, Green S, Hui AC. Biomechanical testing of the locking compression plate: When does the distance between bone and implant significantly reduce construct stability? INJURY. 2007;38(3):358-64.
- 33.Bible JE, Mir HR. External Fixation: Principles and Applications. J AM ACAD ORTHOP SUR. 2015 2015-01-01;23(11):683-90.
- 34.Märdian S, Schaser K, Duda GN, Heyland M. Working length of locking plates determines interfragmentary movement in distal femur fractures under physiological loading. CLIN BIOMECH. 2015;30(4):391-6.
- 35.Ya Ish FMM, Nanu AM, Cross AT. Can DCP and LCP plates generate more compression? The effect of multiple eccentrically placed screws and their drill positioning guides. INJURY. 2011;42(10):1095-100.
- 36.Yang JC, Lin K, Wei H, Chen W, Chiang C, Chang M, et al. Importance of a moderate plate-to-bone distance for the functioning of the far cortical locking system. MED ENG PHYS. 2018;56:48-53.
- 37.Zhang J, Ebraheim N, Li M, He X, Schwind J, Liu J, et al. External fixation using locking plate in distal tibial fracture: a finite element analysis. European Journal of Orthopaedic Surgery & Traumatology. 2015;25(6):1099-104.

Tables

Table 1. Age for three fixation configurations

Construct	Number	Mean (years)	Standard deviation (years)	F- value	P- value
Classical plate-type external fixator	18	33.0	9.6	0.311	0.737
Extended plate-type external fixator	18	31.0	10.9		
Unilateral external fixator	18	35.5	9.2		

Table 2. T-score for three fixation configurations

Construct	Number	Mean	Standard deviation	F- value	P- value
Classical plate-type external fixator	18	-0.81	0.09	0.100	0.905
Extended plate-type external fixator	18	-0.84	0.10		
Unilateral external fixator	18	-0.83	0.09		

Table 3. Axial compression stiffness for three fixation configurations

Construct	Number	Mean (N/mm)	Standard deviation (N/mm)	F-value	P-value
Classical plate-type external fixator	6	1898.8	185.0	24.642	<0.0001
Extended plate-type external fixator	6	1715.8	240.5		
Unilateral external fixator	6	1157.8	129.4		

Table 4. Four-point bending stiffness for three fixation configurations

Construct	Number	Mean (Nm/deg)	Standard deviation (Nm/deg)	F- value	P-value
Classical plate-type external fixator	6	26.7	4.1	17.365	<0.0001
Extended plate-type external fixator	6	24.1	3.6		
Unilateral external fixator	6	15.0	3.0		

Table 5. Torsional stiffness for three fixation configurations

Construct	Number	Mean (Nm/deg)	Standard deviation (Nm/deg)	F-value	P-value
Classical plate-type external fixator	6	3.0	0.2	130.824	<0.0001
Extended plate-type external fixator	6	2.6	0.2		
Unilateral external fixator	6	1.3	0.1		

Table 6. Axial compression strength for three fixation configurations

Construct	Number	Mean (N)	Standard deviation (N)	F-value	P-value
Classical plate-type external fixator	6	2792.2	193.9	56.688	<0.0001
Extended plate-type external fixator	6	2560.5	193.5		
Unilateral external fixator	6	1769.0	128.0		

Table 7. Four-point bending strength for three fixation configurations

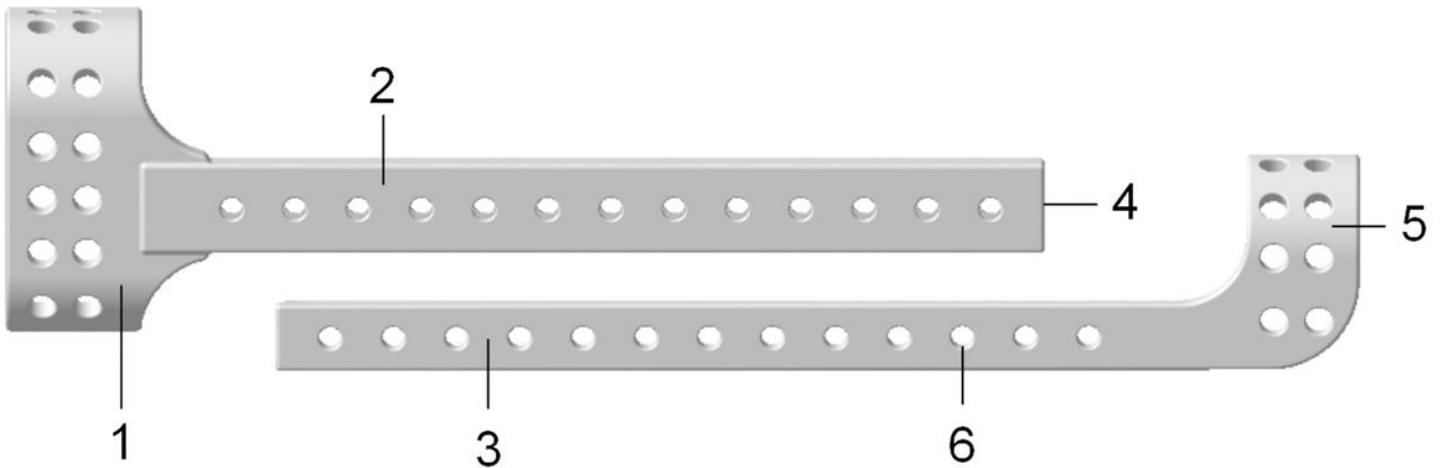
Construct	Number	Mean (Nm)	Standard deviation (Nm)	F-value	P-value
Classical plate-type external fixator	6	58.2	2.0	51.112	<0.0001
Extended plate-type external fixator	6	56.4	1.4		
Unilateral external fixator	6	47.9	2.2		

Table 8. Torsional strength for three fixation configurations

Construct	Number	Mean (Nm)	Standard deviation (Nm)	F-value	P-value
Classical plate-type external fixator	6	34.2	2.3	47.640	<0.0001
Extended plate-type external fixator	6	30.0	1.4		
Unilateral external fixator	6	24.2	1.5		

Figures

a



b

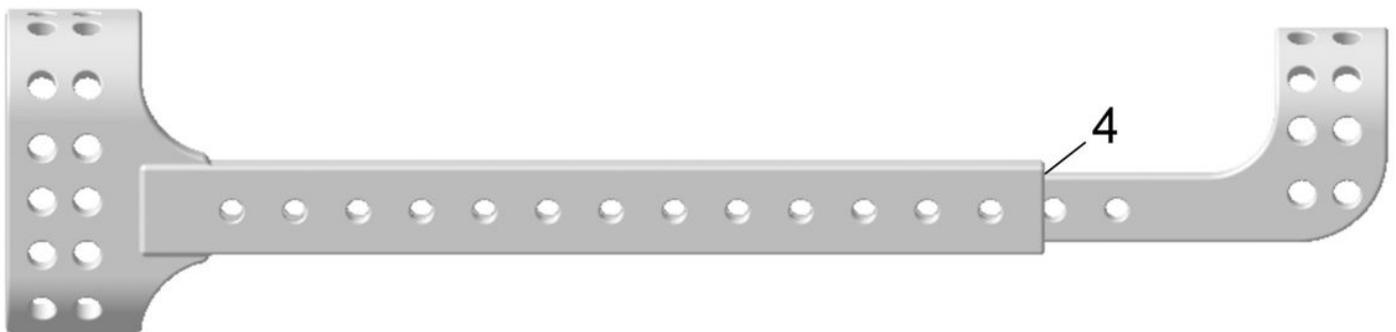


Figure 1

A schematic diagram of the novel external tibial fixation prototype. (a) the partial diagram, (b) the global diagram; (1) the proximal transverse slat, (2) the proximal fixation lath, (3) the distal fixation lath, (4) the slot, (5) the distal transverse slat, (6) the locking screw hole.



Figure 2

A photograph of the fixation configurations potted in polymethylmethacrylate. Left: the unilateral external fixator; middle: the classical plate type external fixator; right: the extended plate type external fixator.

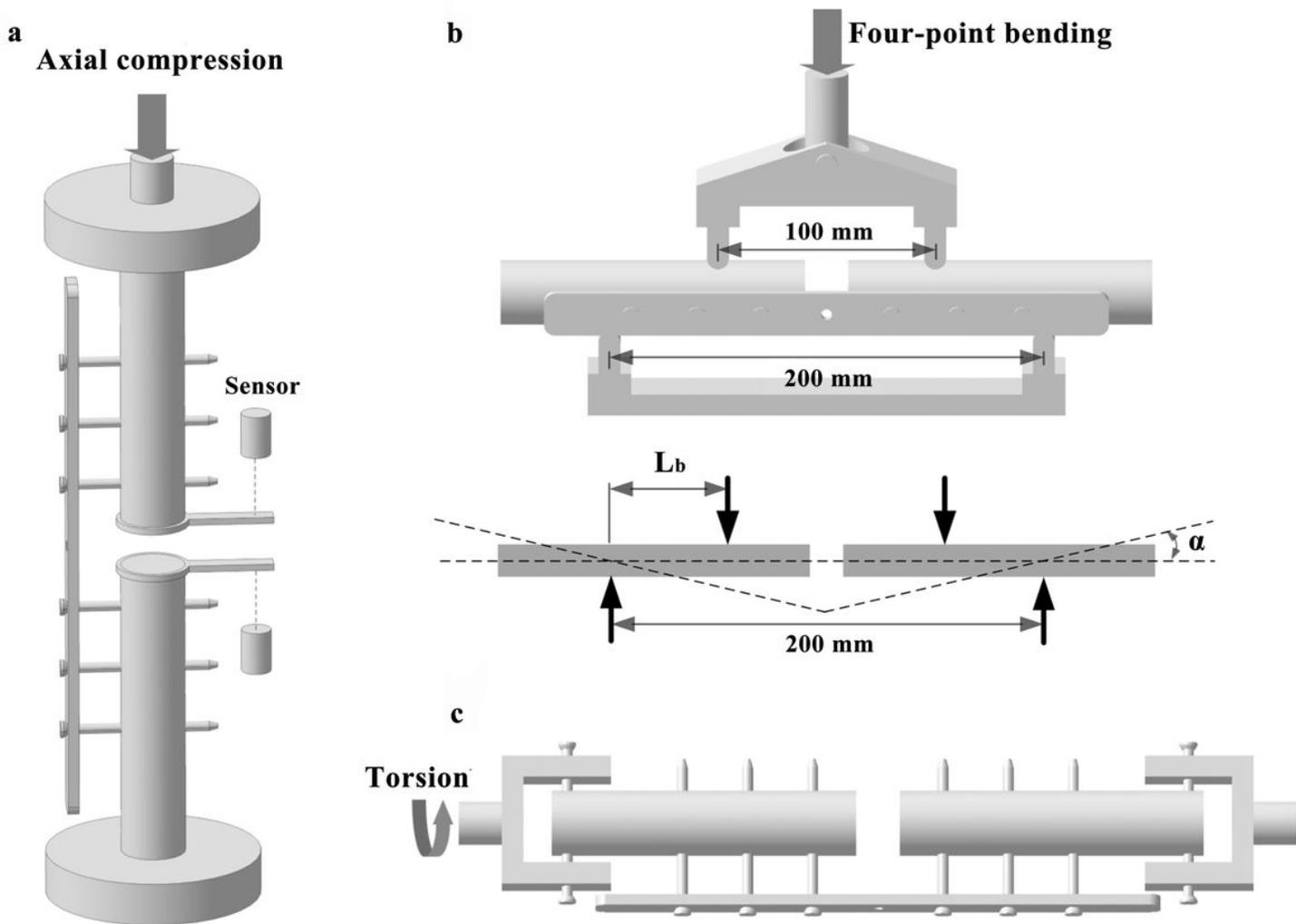


Figure 3

Schematic graphs of the construct stiffness evaluated under three loading conditions. (a) axial compression, (b) four-point bending, (c) torsion. L_b , the bending length, α , the bending angle.

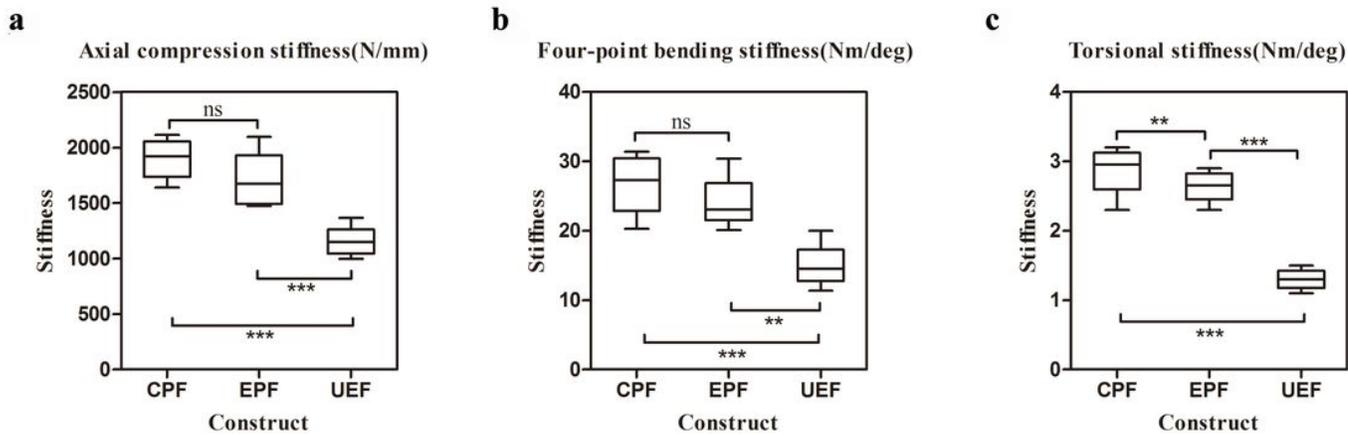


Figure 4

Box plots of the three fixation configurations under axial compression (a), four-point bending (b) and torsion (c). CPF, classical plate type external fixator; EPF, extended plate type external fixator; UEF, unilateral external fixator. ** indicates the statistical significance ($p < 0.01$); *** indicates the statistical significance ($p < 0.001$); ns indicates no significant difference.

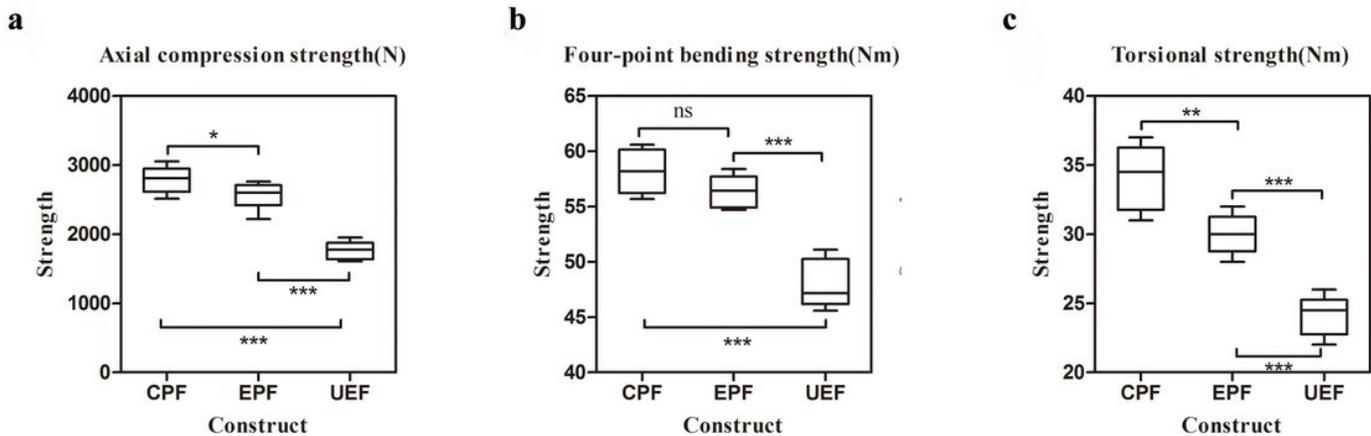


Figure 5

Box plots of the three fixation configurations under axial compression (a), four-point bending (b) and torsion (c). CPF, classical plate type external fixator; EPF, extended plate type external fixator; UEF, unilateral external fixator. * indicates the statistical significance ($p < 0.05$); ** indicates the statistical significance ($p < 0.01$); *** indicates the statistical significance ($p < 0.001$); ns indicates no significant difference.

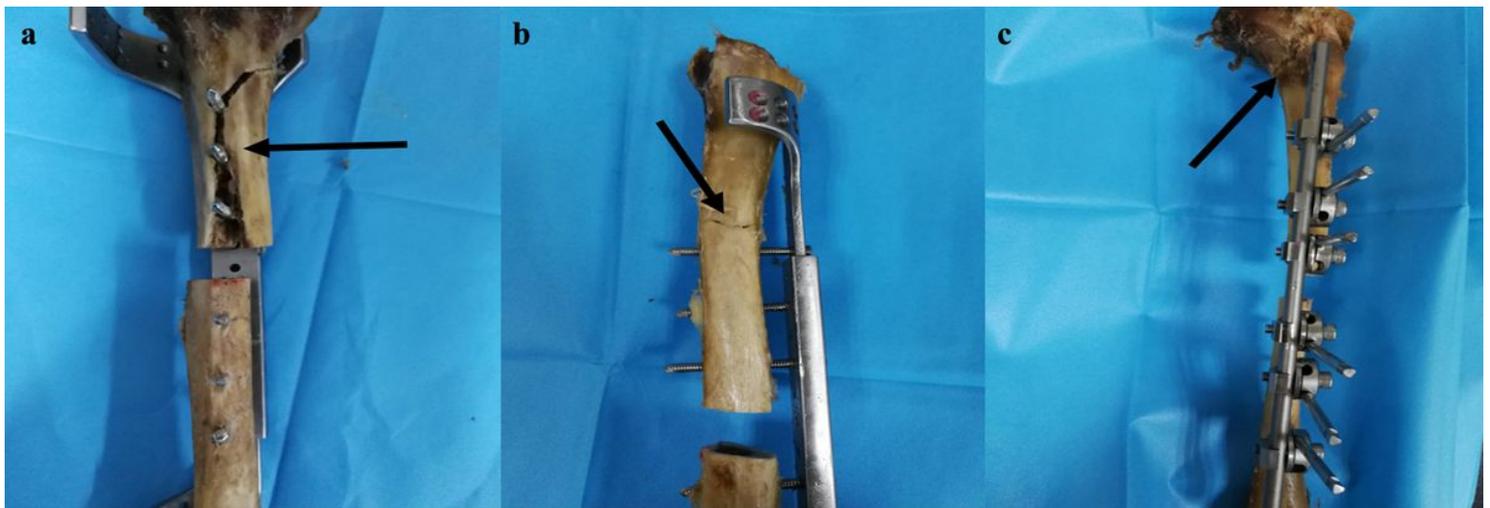


Figure 6

Photographs of the failure modes of configurations for (a) in axial compression, catastrophic fracture of the diaphysis through the screw hole found in classical plate-type external fixator group (indicated by black arrow), (b) in four-point bending, catastrophic fracture of the diaphysis found in extended plate-type external fixator group (indicated by black arrow) and (c) in torsion, oblique fracture found in unilateral external fixator group (indicated by black arrow).